UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM **January 14, 2021**

Subject: Section 18 Risk Assessment for GA and TN Grignard Pure (Triethylene glycol)

PC Code(s): 083501	DP Barcode Number: 459560
Decision No.: 566563	Registration Number: NA
Tracking No(s).: 21TN02, 21GA02	Regulatory Action: Section 18
Risk Assess Type: NA	Case No(s): 3146
TXR No.: NA	CAS No(s): 112-27-6
MRID No(s).: NA	40 CFR: 180.940(a)

From: Timothy Dole, Industrial Hygienist Timothy C. Dole
Timothy F. McMahon, Ph.D., Senior Science Advisor
Kathryn Korthauer, Biologist
Risk Assessment Branch (RAB) I /II
Antimicrobials Division (AD) (7510P)

Digitally signed by MELISSA PANGER
Date: 2021.01.14 17:52:02 -05'00'

Through: Melissa Panger, Ph.D., Branch Chief

Digitally signed by MELISSA PANGER
Date: 2021.01.14 17:52:33 -05'00'

Tim Leighton, Human Health Senior Scientist
Judy Facey, Ph.D., Human Health Risk Assessment Process Leader

JUDY FACEY Digitally signed by JUDY FACEY Date: 2021.01.14 17:48:34 -05'00'

Andrew Byro, Ph.D., Ecological Risk Assessment Process Leader

ANDREW BYRO Digitally signed by ANDREW BYRO Date: 2021.01.14 17:44:51 -05'00'

Risk Assessment Branch (RAB I/II)
Antimicrobials Division (AD) (7510P)

To: Andrea Conrath, Biologist
Daniel Rosenblatt, Acting Branch Chief
Minor Use and Emergency Response Branch
Registration Division (AD)(7505P)

1.0 Introduction

Grignard Pure is proposed as a new emergency use (Section 18) use of an air disinfectant containing the active ingredient (a.i.) triethylene glycol (TEG) in the states of Georgia and Tennessee. It is designed to reduce the airborne level of the following airborne microorganisms:

- SARS-CoV-2 based on testing with a surrogate virus;
- All influenza virus strains.

2.0 Proposed Product and Use Pattern

Grignard Pure (52.25% a.i.) is a ready to use liquid that is to be applied undiluted via HVAC systems or portable devices using only Grignard Pure-certified air treatment equipment. The label (see Appendix A) proposes uses in the following indoor occupied spaces, including:

- Health care facilities (except in resident / in-patient rooms, emergency rooms, operating rooms, and intensive care units);
- Intrastate buses, trains, and subways;
- ice rinks;
- food processing facilities;
- indoor spaces, including government facilities where people are conducting activity deemed essential by the state (links to specific state listings will be provided at www.GPCustomer.com/EssentialActivities.)

The label indicates that the amount of Grignard Pure product required to maintain proper levels will vary depending on the following parameters:

- Size of room or interior space;
- Air exchanges per hour;
- Temperature and humidity; and
- Hours of operation for your office/facility/venue.

The applications will be made using the HVAC system or using portable devices. Where Grignard Pure equipment is integrated into a building's HVAC system, the installation must be performed by a Grignard Pure-certified installer. Greatest efficiency is achieved when the equipment is connected directly to the HVAC unit controls, so that the equipment will turn on when the HVAC equipment has a call for operation. When applications are made using portable devices, the Grignard Pure equipment is placed in strategic locations in an interior space. The proposed label requires that the specific equipment placement be determined by a Grignard Pure-authorized dealer or Grignard Pure-certified installer.

The proposed application rate is 1.04 mg TEG/m^3 to 5.62 mg TEG/m^3 to produce a time weighted average (TWA) of 3 mg TEG/m^3. These concentrations correspond to a range of non-visible to light haze and can be maintained using sensors or by visual observation. The sensor must be a Grignard Pure-certified sensor, purchased through and installed by a Grignard Pure-authorized dealer or Grignard Pure-certified installer. When using the visual observation method, a light haze air treatment level is maintained by running the device for a few minutes, every 30 minutes (times will vary depending upon unique equipment output and volume of area to be treated). Based on information provided in the submission, the observation of a very light to

light haze in the air will confirm proper levels of product concentration for achieving effective, continuous levels of air treatment. Recommended frequency of visual assessment monitoring is at least once every hour. Table 1 provides the minimum and maximum application rates and associated visual haze densities and particle sensor readings included on the proposed label.

Table 1. Proposed Minimum and Maximum Application Rates for GP and TEG.

Application Rate	Measurement Method		Equivalent TEG Concentration
	Visual Assessment of Haze Density	Particle Sensor Reading for GP	
Minimum	Non-visible	1.66 mg/m^3	1.04 mg/m^3
Maximum	Light Moderate	9 mg/m^3	5.62 mg/m^3

GP = Grinard Pure

Continuous Machine Use

Do not run equipment for more than 12 hours of continuous operation in a 24-hour period. At 12 hours, turn the equipment off and maintain air circulation to ensure any Grignard Pure residue in the filter has dried out.

Comparison to Existing Uses

The proposed use patterns in this Section 18 memo for Grignard Pure are similar to the existing 12 TEG registered products as automatic and manual space sprays with differences being the scale of the applications (e.g., method of application, application rates, and durations of exposures to individuals). Appendix B provides more details on the existing products.

3.0 Hazard Characterization

The Agency previously characterized the human health hazard of triethylene glycol (TEG) in the 2005 Reregistration Eligibility Decision document (RED) (USEPA 2005). The toxicity of TEG was also summarized in the 1993 British Industrial Biological Research Association (BIBRA) Toxicity Profile for Triethylene Glycol (BIBRA 1993). Human health hazard of TEG was also characterized in the 2017 proposed interim decision for propylene glycol, dipropylene glycol, and TEG (EPA-HQ-OPP-2013-0218 and EPA-HQ-OPP-2013-0219; https://www.regulations.gov/searchResults?rpp=25&po=0&s=EPA-HQ-OPP-2013-0218&fp=true&ns=true; https://www.regulations.gov/searchResults?rpp=25&po=0&s=EPA-HQ-OPP-2013-0219&fp=true&ns=true

The previous assessments by the Agency concluded that that there were no endpoints of concern for systemic effects from oral, dermal, or inhalation exposure to triethylene glycol. This conclusion was based on the results of toxicity testing of TEG in experimental animals in which no significant adverse effects were observed at dose levels near or above testing dose limits.

The 1993 BIBRA Toxicity Profile for TEG reported adverse systemic effects in experimental animals only at oral and inhalation doses near or above testing limits. There was no evidence of reproductive or developmental toxicity of TEG in the database. TEG is also negative for carcinogenicity.

It should be noted that the data cited for inhalation hazard of TEG from repeated exposure are older (Robertson et al., 1947) and contain several deficiencies in relation to the Office of Pesticide Programs' 2012 Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment (USEPA, 2012). Specifically, data are lacking on the characterization of the test material, there are missing analytical data on test atmospheres, an insufficient number of dose levels was tested, and poor health status of animals was observed. A published report by Ballantyne et al. (2006) is the best available study on repeat dose inhalation toxicity of TEG. This study consisted of an acute 4-hour inhalation exposure, a 9-day whole body inhalation exposure experiment and a 9-day nose-only inhalation exposure experiment. A summary of the available inhalation toxicity data is shown in Table 2 below.

Table 2. Inhalation Toxicity Profile of Triethylene Glycol

Study Type	Concentrations Tested	Results
Inhalation: 4-hour – rat Ballantyne et al. (2006)	2620, 3900, 5020, 6730 mg/m^3 whole body exposures	Mortality at 5020 mg/m^3; absence of toe and tail pinch reflexes at 5020 and 6730 mg/m^3; Perioral/perinasal encrustation at all concentrations.
Inhalation: 9-day – rat Ballantyne et al. (2006)	494, 2011, 4824 mg/m^3 – whole body exposure; 6 hrs/day, 5 days/week total of 9 (days) exposures	All rats died at 4824 mg/m^3; Periocular swelling and perinasal encrustation at 494 and 2011 mg/m^3; increased alanine aminotransferase in males at 2011 mg/m^3; significant increase in urine volume, decrease in urine pH, increase in *N*-acetyl-β-D-glucosaminidase at 2011 mg/m^3; increased relative liver and kidney weight at 2011 mg/m^3.
Inhalation: 9-day – rat Ballantyne et al. (2006)	102, 517, 1036 mg/m^3 nose-only exposure, 6 hrs/day, 5 days/week total of 9 (days) exposures	Decreased body weight gain (15%) at 1036 mg/m^3; no other effects observed at any concentration.

Ballantyne et al. (2006) studied the acute inhalation toxicity of TEG by the inhalation route in rats. These 4-hour exposures showed only perioral and perinasal encrustation after exposure to concentrations ranging from 2620-6730 mg/m^3 in rats.

Ballantyne et al. (2006) also examined effects from repeated inhalation exposures to TEG by both whole-body and nose-only experiments in rats. Both experiments were for six hours per day, 5 days per week for a total of 9 days exposure.

In the first experiment, Sprague-Dawley rats were exposed whole body to TEG in an aerosol inhalation study at concentrations of 494, 2011, or 4842 mg/m^3 for six hours a day, 5 days a week, nine (days) times over a two-week period. At the highest concentration of 4842 mg/m^3, ataxia, prostration, unkept fur, labored respiration (males only), ocular discharge, swollen periocular tissue, perinasal and perioral encrustation, blepharospasm and reduced body weights were observed. Necropsy revealed hyperinflation of the lungs, ocular opacity, congestion and hemorrhage in many organs and tissues (pituitary gland, brain, nasal mucosa, kidney, thymus and lungs). All of the rats in the high dose group died or were sacrificed moribund by day 5 of the study.

Clinical signs of toxicity observed at the low- and mid-dose of 494 and 2011 mg/m^3/day, respectively, were limited to swollen periocular tissues and perinasal encrustations. Treatment-related changes in organ weights in mid-dose males included an increase in liver and kidney weights relative to body weight; mid-dose females showed increases in absolute and relative (to body and brain weights) liver and kidney weights. Statistically significant clinical chemistry findings for males treated with 2011 mg/m^3/day triethylene glycol included an increase in alanine aminotransferase (ALT) activity and a decrease in serum creatinine levels. Mid-dose females showed increases in urea nitrogen, inorganic phosphorus, ALT and alkaline phosphatase (ALK) activity, and decreases in glucose, creatinine, and chloride. However, the changes in organ weights and clinical chemistry findings were not correlated with any histopathological observations.

It was hypothesized that the whole-body exposure to TEG may have resulted in potential oral exposures from preening of the fur, in addition to inhalation exposures. To obtain a better evaluation of TEG toxicity by the inhalation route, a second inhalation toxicity study was conducted to determine the inhalation-routes' contribution to toxicity using a nose-only exposure for 6 hours a day, 9 consecutive days. In this second inhalation toxicity study, mean exposure concentrations of 102, 517, or 1036 mg/m^3 triethylene glycol produced no treatment-related toxicities at any dose tested.

As noted above, Robertson et al. (1947) examined effects of inhalation exposure to TEG in both rats and monkeys at concentrations of TEG that saturated the air. Concentrations were stated to be in the range of 2.5-5 mg/m^3 for rats and monkeys, but the concentrations of TEG could not be verified from the data in this study. Exposure durations ranged from 3 to 13 months. While no significant adverse effects were reported in the exposed rats and only increased mortality in monkeys was reported in this study, several deficiencies were noted, making the data unacceptable for use in a qualitative or quantitative assessment of inhalation hazard and risk.

Based on the available inhalation-route specific toxicity data, there is uncertainty regarding exposures durations longer than the Ballantyne et al. study's 9-day exposure period (*i.e.*, intermediate- and long-term exposure durations) that would not produce adverse effects by inhalation.

Studies that examined a potential association between inhalation exposure to glycols (including TEG) and irritation effects in theatrical workers and actors to vapors of glycols during various theatrical productions stage performers (NIOSH, 1994; Moline et al. 2000) were also found to have several deficiencies for use either qualitatively or quantitatively in TEG inhalation assessments. Exposures were to mixtures of glycols with the presence of mineral oil in some cases, making it difficult to ascribe any adverse effects to TEG alone. In addition, a repeated exposure level to TEG that was without adverse effect on irritation was not described; it was only noted in the Moline et al. 2000 report that peak exposure to glycol mixtures not exceed 40 mg/m^3, but this recommendation is only for peak exposure (not the time weighted average over the timeframe of the study which would have been less than the peak of 40 mg/m^3).

The information summarized above was also discussed in a letter submission by William Jordan, consultant to Grignard Pure, LLC, and Jack Caravanos, Clinical Professor at NYU School of Global Public Health, dated December 17, 2020. This letter also discussed the available inhalation toxicity data for TEG, including the studies of Robertson et al. (1947) and Ballantyne et al. (2006).

In addition to the animal studies already discussed, human exposure to glycols and/or TEG in the film and stage performance industry at stated concentrations of 6-7 mg/m^3 "over the course of several weeks' and "up to 40 mg/m^3 of TEG-based fog for up to 10 hours a day for 20 plus years" is also stated. Letters from professionals in the film and stage industries are also provided, where short-term irritation effects (irritation of the eyes, dryness of the sinuses and mouth) are stated, which are also stated to subside after leaving the stage where such glycol-based fog effects are used. These statements are summary information only, and the letters do not contain supporting quantitative air concentration measurements or reported statistical associations.

There are stated inhalation exposures of 10 mg/m^3 for 8 hours of exposure and 40 mg/m^3 for peak exposures to TEG that are mentioned in a letter submitted from Justin Krauss, Special Effects Coordinator for Revolution Effects. These values are exposure guidelines set forth by the Entertainment Services and Technology Association (ESTA, 2018). There are no data in that document supporting derivation of these values.

4.0 Incident Reports

In the Final Workplan for the Registration Review of Propylene Glycol, Dipropylene Glycol and Triethylene Glycol (U.S. EPA, 2013), it is stated that there are 413 incidents which have been reported in the OPP Incident Data System (2001 – 2012) which have been associated with exposure to triethylene glycol. Of these cases, 392 are associated with EPA Reg. No. 4822-293, which is pressurized liquid aerosol can formulation that contains 6% TEG as the active ingredient used as a space spray. The highest number of incidents reported per year was 183 for 2002 and 58 for 2003. The incidents reported for the remaining years ranged from 11 for 2011 to 42 for 2005. Most of the incidents reported for the years 2002 and 2003 were associated with a test market version of product 4822-293 and are reported in Incident Packages I012445 and I012570. It is not known why these incidents decreased after 2003.

There are 13 incidents for TEG listed in the OPP Incident Database System for the time period 1/1/2012 to the present (search conducted on 12/09/2020). Eleven of these incidents involved products that also contain the quarternary ammonium chemical n-Alkyl (40% C_{12}, 50% C_{14}, 10% C_{16}) dimethyl benzyl ammonium saccharinate (ADBAS) and one of these incidents involves a product that also contains pyrethroid insecticides. In the one incident where the product only contained TEG, the caller experienced decreased mental function and grogginess after applying the product to the floor of his home and then puncturing the product container.

5.0 Human Exposure Assessment

There is the potential for occupational and residential post application inhalation exposures for persons who work or live in treated areas. The occupational (*i.e.*, worker) exposures can occur in areas such as health care facilities, food processing facilities, ice rinks, mass transit facilities and government facilities. These exposures can occur throughout the workday which is assumed to last 8 hours (or 12-hour shifts if hospitals). The residential exposures are anticipated to be a few hours per day when applications are made in areas such as ice rinks and mass transit facilities; however, these exposures may be of longer daily duration when applications are made in areas such as nursing homes, social service facilities and correctional facilities.

Although many of the exposures are anticipated to be of short (up to 1 month) to intermediate (1 to 6 months) term durations, long term exposures for some of the uses such as in health care facilities (*e.g.*, hospitals, nursing homes, medical offices, dental offices) may result in exposures to residents of nursing homes or the workers in hospitals, etc. to be exposed for greater than 6 months.

6.0 Dietary Assessment

There is the potential for dietary exposure as a result of indirect food contact with residues of TEG on surfaces when the product is used as an antimicrobial air treatment in locations such as food processing facilities, cafeterias, and food preparation areas. However, due to the lack of observed adverse effects from oral exposures to triethylene glycol at oral doses at or exceeding a limit dose, dietary risk from indirect food contact is not expected.

At the time of the last TEG risk assessment, it was noted that a tolerance exemption was needed. On November 3, 2020 the Environmental Protection Agency (EPA or the Agency) posted a federal register notice notifying the public it was "exempting residues of the antimicrobial pesticide ingredients dipropylene glycol and triethylene glycol from the requirement of a tolerance when used on or applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. The Agency finalized this rule on its own initiative under the Federal Food, Drug, and Cosmetic Act (FFDCA) to address residues identified as part of the Agency's registration review program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)." (FR Doc 2020-23199). The regulation was effective November 3, 2020 and was codified in 40 CFR Section 180.940(a), covering the use of triethylene glycol as an antimicrobial air treatment. Therefore, no additional tolerance or tolerance exemption is needed.

7.0 Environmental Assessment

Based on the proposed indoor uses and the low toxicity of TEG, risks to terrestrial and aquatic non-target organisms are not expected. Ecological effects data were previously waived by the Agency due to the use of TEG's known low toxicity to terrestrial and aquatic organisms (USEPA, 2005). As discussed in the RED (USEPA, 2005), data obtained from published studies provide additional confirmation of the low toxicity of the compound to fish and aquatic invertebrates. Furthermore, TEG is readily biodegradable and is volatile and would result in limited aquatic exposure potential for any TEG that may be released from the proposed indoor uses. Therefore, risks to non-target organisms are not expected for TEG with respect to the use patterns proposed here.

8.0 Conclusions

The proposed product Grignard Pure, containing the a.i. of triethylene glycol (TEG), is an application for a Section 18 emergency exemption in the state of Georgia and Tennessee which is to be applied as a mist recognizable as a non-visible to light haze corresponding to an air concentration of 1.04 to 5.62 mg TEG/m^3. The proposed use is intended to be used when people are present as a treatment designed to reduce the airborne levels of SARS-CoV-2 based on testing with a surrogate virus as well as all influenza virus strains.

Based on reliable data, the available toxicity profile for TEG shows no hazard identified from oral studies at doses significantly above the limit dose up to 90 days in the rat. Thus, EPA does not expect systemic toxic effects from TEG exposures up to intermediate- and long-term exposures from any route of exposure. For inhalation exposures, the available toxicity data for TEG do not support an evaluation of repeated inhalation exposures of intermediate- or long-term duration. It is known that repeated inhalation exposure up to 9 days shows no significant adverse systemic effects in experimental animals. There remains uncertainty in the irritation potential of TEG from exposure longer than 9 days. The available inhalation toxicity data do not support an evaluation of irritation potential for TEG from exposures longer than 9 days. This is relevant for occupational workers, who will be exposed on a more continuous basis to TEG in the air than intermittent exposures that would be expected from persons visiting locations that have been or are being treated with TEG. Therefore, an assessment of long-term inhalation exposure to TEG is not currently supported.

Although there is the potential for TEG residues to contact food preparation surfaces, there are no dietary endpoints of concern, and therefore, no dietary risks of concern. Additionally, based on the proposed indoor uses, there is limited exposure potential for on-target terrestrial and aquatic organisms.

9.0 References

BIBRA (1993): Toxicity Profile: Triethylene Glycol. BIBRA Toxicology Advice and Consulting. Epsom, Surrey, UK.

Ballantyne, B., Snellings, W.M., Norris, J.C. (2006): Respiratory peripheral chemosensory irritation, acute and repeated exposure toxicity studies with aerosols of triethylene glycol. *J. Appl. Toxicol*. 2006; **26**: 387–396.

ESTA (2018): Entertainment Technology- Theatrical Fog made with Aqueous Solutions of Di- and Tri-hydric Alcohols.

Moline, J.M (2000): Health Effects Evaluation of Theatrical Smoke, Haze, and Pyrotechnics. Report prepared for Equity-League Pension and Health Trust Funds.

NIOSH 1994. Health Hazard Evaluation #HETA-90-0355-2449, Actor's Equity Association/The League of American Theatres and Producers, Inc., New York, New York. August 1994.

Robertson, O.H.; Loosli, C.G.; Puck, T.; Wise, H.; Lemon, H.; Lester, W. (1947): Tests for the Chronic Toxicity of Propylene Glycol and Triethylene Glycol on Monkeys and Rats by Vapor Inhalation and Oral Administration. J. Pharmacol. Exp. Ther. 91: 52-76.

FR Doc 2020-23199. Dipropylene Glycol and Triethylene Glycol: Exemption from the Requirement of a Tolerance. Environmental Protection Agency. RIN 2070-ZA16. Dockets: EPA-HQ-OPP-2013-0218 and EPA-HQ-OPP-2013-0219. FRL-10015-39. Filed 11-2-20; 8:45 am. https://www.govinfo.gov/content/pkg/FR-2020-11-03/pdf/2020-23199.pdf [Last Retrieved Dec 10, 2020]

U.S. EPA (2005): Reregistration Eligibility Decision for Triethylene Glycol.

U.S. EPA (2012): Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment.

U.S. EPA (2013): Final Workplan for the Registration Review of Propylene Glycol, Dipropylene Glycol and Triethylene Glycol. December 2013. Posted to Docket #s EPA-HQ-OPP-2013-2018 and EPA-HQ-OPP-2013-0219 at Regulations.gov.

Appendix A Master Label

GRIGNARD PURE.
ANTIMICROBIAL AIR TREATMENT

UNREGISTERED PRODUCT

For Sale, Distribution, and Use under a Public Health Emergency Exemption only in the States listed on the back panel

Product Storage: Store in a cool, dry, ventilated area. Keep container tightly closed and properly labeled.
Product Disposal: Follow Federal, State, provincial and local Government requirements for waste. Do not contaminate water, food, or feed by storage or disposal.
Container Disposal: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.
Following expiration of exemption: Sealed, unopened product must be returned to Grignard Pure, LLC or its distributors.

Grignard Pure, LLC
505 Capobianco Plaza
Rahway, NJ 07065

EPA Est. No 96156-NJ-1

REQUIRED
Post stickers or signs at each entrance to and interior of a treated space.

Signs/stickers provided at time of installation.

Precautionary Statements:
Avoid contact of skin and clothing with liquid product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

Exposure Parameters:
Do not apply product in a way that results in exposure to any individual for more than 12 hours in a 24-hour period.

FIRST AID	
If in eyes while handling the liquid product:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye(s) • If irritation persists, seek medical assistance
If on skin while handling the liquid product:	• Rinse skin immediately with plenty of water for 15-20 minutes • If irritation persists, seek medical assistance
If swallowed	• Do NOT induce vomiting • Seek medical assistance

Have the product container or label with you when calling a doctor or going for treatment.
24 Hour Emergency Telephone Contact Number: CHEMTREC: 1-800-424-8300
Information – Comments: 1-855-642-PURE (7873).

Attention: Air treatment may activate photoelectric smoke detectors. Dense air treatment may activate Ionization smoke detectors. Air Treatment will not activate heat sensor fire detectors. At all times fire monitoring systems must be in use in accordance with local, State and Federal requirements.

Air treatment does not damage surfaces or harm electronic equipment. When used properly the product does not create slip and fall situations.

Shelf Life: Product is stable in an unopened sealed container for 3 years. Once opened product is stable for one year if the cap is closed when the product is not in use.

GRIGNARD PURE™

Continuous Antimicrobial Air Treatment

Kills 98% of airborne SARS-CoV-2 virus when in use.
For indoor use only in both occupied and unoccupied spaces.

Follow SARS CoV-2 risk mitigation guidelines issued by Federal, State and local public health officials. Grignard Pure is not to be relied upon as a sole mitigation but is a supplemental treatment to be used in conjunction with current public health guidelines. See **Directions for Use** for specific details regarding criteria for use of this product.

CAUTION:
KEEP OUT OF REACH OF CHILDREN

Read the entire label before using. Follow all applicable directions, requirements, and precautions. Any adverse effects from the use under these exemptions must immediately be reported to the manufacturer: 1 (855) 642-PURE (7873).

ACTIVE INGREDIENT
Triethylene Glycol……..52.25%
INERT INGREDIENTS……47.75%
TOTAL……100.00%
Patent Pending

Net Content **1 Gallon (3.78L)**

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Handling: After handling, always wash hands thoroughly with soap. Wipe up spills immediately to avoid slips and falls.

Grignard Pure is designed to reduce the level of airborne SARS-CoV-2 virus, based on testing with a surrogate virus.

Grignard Pure is for use with only Grignard Pure-certified air treatment equipment and sensors. Read and follow the User Manuals for complete directions on how to operate this equipment (Manuals and more information available at www.GPCustomer.com/Solutions.)

Grignard Pure is to be used in full concentration and cannot be diluted.

For use only in the following listed indoor spaces (occupied or unoccupied) when adherence to current public health guidelines (e.g., CDC guidance at www.cdc.gov recommending face masks, social distancing, limited occupancy, and increased ventilation) is impractical, difficult to maintain, or is not expected to provide a sufficient level of protection. Areas of particular concern include breakrooms, locker rooms, bathrooms, lobbies, elevators, eating areas, and food preparation areas within:

- Health care facilities (e.g., hospitals, nursing homes, medical offices, dental offices), except the following:
  - Resident / in-patient rooms;
  - Emergency rooms including waiting areas;
  - Operating rooms;
  - Intensive care units.
- Intrastate buses, trains, and subways;
- Food processing (NAICS 311) but not food services (NAICS 722);
- Indoor spaces within buildings, including government facilities, where people are conducting activity deemed essential by the state and allowed by the state lead agency on this label, unless excluded above.

The amount of Grignard Pure product needed to maintain required levels (see Table 1) will vary depending on the following parameters (confer with your Grignard Pure-authorized dealer or Grignard Pure-certified installer to confirm specific requirements for your system):

- Size of room or interior space;
- Air exchanges per hour;
- Temperature and humidity;
- Hours of operation for your office/facility/venue.

Standard Machine Set-up and Use:

Machines and equipment used must be certified by Grignard Pure and-installed by Grignard Pure-certified installers. Use with any other machines, equipment, or systems is prohibited. Consult with your Grignard Pure-authorized dealer or Grignard Pure-certified installer to determine optimal installation specifications for your indoor space, to include: portable device vs. HVAC integration; number and placement of devices; sensor technology for maintaining required levels vs. visual observation.

There are two types of machine implementation and use:

HVAC integration: Where Grignard Pure equipment is integrated into a building's HVAC system, this installation MUST be performed by a Grignard Pure-certified installer.

Greatest efficiency is achieved when the equipment is connected directly to the HVAC unit controls, so that the equipment will turn on when the HVAC equipment has a call for operation.

Portable device equipment: When Grignard Pure equipment is used, the specific equipment placement shall be determined by a Grignard Pure-certified installer.

In both cases, equipment must be operated, cleaned and serviced in accordance with the User Manual.

For maximum effectiveness, the best achieved air treatment level will be reached when the temperature is between 65°F-80°F and relative humidity is between 25%-60%.

Measuring Proper Product Concentration Levels

Apply the product to achieve an airborne concentration of Grignard Pure according to Table 1 below.

Measurement Method	Visual Assessment of Haze Density	Particle Sensor Reading for GP	Equivalent Active Ingredient Concentration
Minimum	Non-visible	1.66 mg/m^3	1.04 mg/m^3
Maximum	Light Moderate	9 mg/m^3	5.62 mg/m^3

There are two methods for ensuring a proper concentration of Grignard Pure in the air:

Sensors: Maintain a concentration between 1.66 mg/m³ to 9 mg/m³ to produce a Time Weighted Average below 4.8mg/m^3 of GP [3mg/m^3 AI] as measured by a certified sensor, purchased through an authorized dealer and installed by a certified installer. (These concentrations correspond to a range of non-visible to light moderate haze.)

Visual Observation: For installations where concentration is not sensor-controlled, visual assessment must replace the use of sensors. Maintain a light air treatment level by running the device for a few minutes, every 30 minutes (Times will vary depending upon the specific equipment output, and volume of space to be treated.) In this method, the observation of a very light to light haze in the air will confirm proper levels of product concentration for achieving effective, continuous levels of air treatment. Refer to www.GPCustomer.com/Visual Assessment for directions on how to effectively perform visual assessment. Recommended frequency of visual assessment monitoring is at least once every hour.

Recommended:

Maintain HVAC circulation at all times to ensure any Grignard Pure residue in the filter has dried out.

GRIGNARD PURE.
ANTIMICROBIAL AIR TREATMENT

UNREGISTERED PRODUCT

For Sale, Distribution, and Use in the following States only in accordance with the FIFRA §18 Public Health Emergency Exemptions listed below:

State and §18 Emergency Exemption Number	Effective Dates
Tennessee Department of Agriculture: 21TN02	01/14/21 – 1/13/22
Georgia Department of Agriculture: 21GA02	01/14/21 – 1/13/22

PURE
Grignard Pure, LLC
505 Capobianco Plaza
Rahway, NJ 07065

Appendix B – Summary of Currently Registered Uses of TEG

There are 12 products that contain TEG as an active ingredient (a.i.). These products are formulated as pressurized liquids that contain 4.4 to 30.84 percent TEG. Seven of these products contain only TEG while 5 products also contain other a.i.s such as propylene glycol (one product), ADBAS (two products), ADBAC (one product) and cypermethrin (one product). The products that contain only TEG or TEG and propylene glycol are used only for air deodorization treatment, while the products that contain TEG with ADBAS or ADBAC are also used for surface treatment. The product that contains cypermethrin is a total release fogger.

The products are packaged in aerosol spray cans that range in size from 0.8 to 20 ounces. The cans can be manually activated, or they can be placed in automatic spray devices. The use directions for the manually activated applications typically specify a ten second spray for an average sized room (12 feet by 12 feet by 9 feet) and that the sprays should be applied as needed or several times per day. The use directions for the automatic sprayers typically specify that one unit will treat a certain size space for one month of sprays applied at 5 or 15-minute intervals.

The average TEG air concentrations for two representative products applied as a handheld space spray (EPA Reg. No. 4822-293) and as an automatic space spray (EPA Reg. No. 10807-430) are listed in Table 1. These air concentrations were calculated using the Well Mixed Box (WBM) model (Formula D.1 in U.S. EPA, 2012) and the resulting concentration profiles are included in Figures 1 and 2. These air concentrations only consider the removal by ventilation and do not consider removal by particle settling. The automatic sprayer product label indicates that the product is applied as an "Extremely Fine Dry Mist Spray with Little Fall Out to "Rain" on Floor" which suggests that minimal particle settling would occur.

The 24-hour air concentration of 10.7 mg/m^3 for the handheld space spray applications is greater than the maximum application rate of 5.62 mg/m^3 for Grignard Pure. In addition, the Grignard Pure label specifies that the applications can only be made for 12 hours per day which would cause the 24-hour average concentration to be less than 5.62 mg/m^3. The 24-hour air concentration of 0.24 mg/m^3 for the automatic space spray applications is less than the minimum application rate of 1.04 mg/m^3 for Grignard Pure.

Table 1 – Average TEG Air Concentrations for Currently Registered Products

Application Type	TEG in Spray (% a.i.)	Application Instructions	Initial TEG Air Concentration (mg/m^3)	Ventilation Rate[B] (ACH)	24 Hour Average TEG Air Concentration (mg/m^3)
Handheld Space Spray	6.0	Spray ten seconds in a 12' x 12' x 9' room (1296 ft^3 or 36.7 m^3)	16.3[A]	0.45	10.7[C]
Automatic Space Spray	5.5	One unit treats a 6000 ft^3 space every 15 minutes for one month. (3000 sprays)	0.025	0.45	0.24[D]

A. Based on a product discharge rate of 1 gm/sec measured in the AEATF Aerosol Can Study MRID 48659001.
B. Standard ventilation rate in Air Changes per Hour (ACH) used to assess residential exposures (U.S. EPA, 2012a).
C. 24-hour Time Weighted Average assuming 7 sprays applied per day (Figure 1).
D. Steady state average concentration reached during the first day of application and maintained for 31 days (Figure 2).

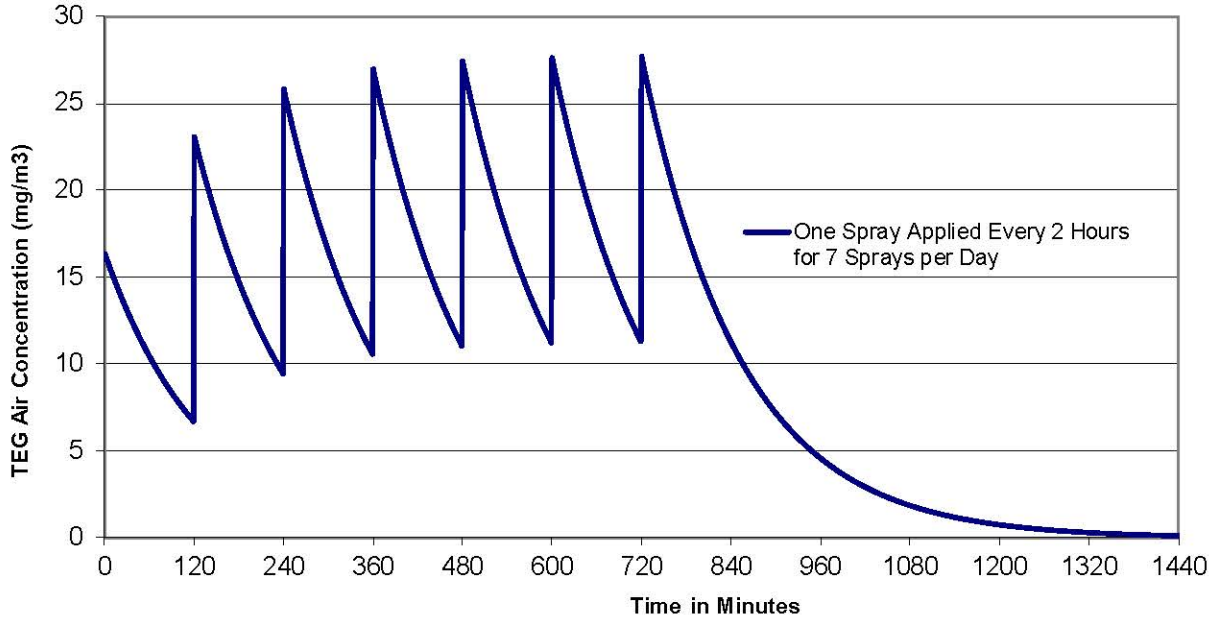

Figure 1- Handheld Aerosol Can TEG Air Concentration (EPA Reg. No. 4822-293)

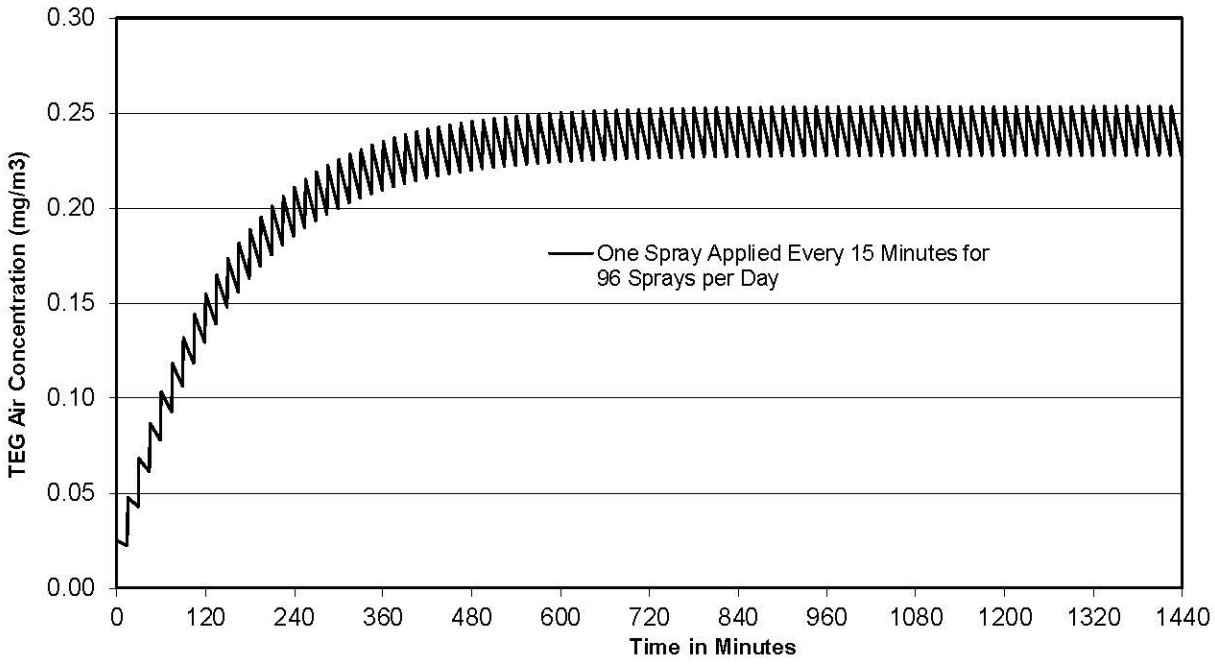

Figure 2 – Automatic Sprayer TEG Air Concentration (EPA Reg. No. 10807-430)

Appendix B References.

MRID 48659001. A Study for Measurement of Potential Dermal and Inhalation Exposure during Application of a Liquid Antimicrobial Pesticide Product Using a Pressurized Aerosol Can for Indoor Surface Disinfecting. AEATF II Project ID: AEA04. November 14, 2011.

U.S. EPA (2012a): Standard Operating Procedures for Residential Pesticide Exposure Assessment. Office of Pesticide Programs. Health Effects Division. October 2012.